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DEPT. OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	<b>APPLICATION FOR A VARIANCE          FROM 21 CFR 1040.11 (c) FOR A          LASER LIGHT SHOW, DISPLAY          OR DEVICE</b>	Form Approved No. 57R0068  <b>DOCKET NUMBER</b>
NOTE: No laser light show or display device may vary from compliance with 21 CFR 1040.11(c) in design or use without the approval of the application in accordance with 21 CFR 1010.4.		
<b>INSTRUCTIONS</b> 1. Check all applicable boxes and type or print the requested information.    3. Mail your application to the Hearing Clerk, Food and Drug Administration Room 4-85, 5600 Fishers Lane, Rockville, MD 20857 2. Submit an original and four (4) copies.    4. Enter Docket Number if assigned.		
1. NAME OF COMPANY Family Bowling Center		
2. ADDRESS OF COMPANY (Include ZIP Code) 3599 5th Ave South P.O. Box 687 Fort Dodge, IA 50501		
3. NAME OF RESPONSIBLE PERSON Rick Harrington	4. TELEPHONE NO. (Include area code) (515) 576-7664	5. DATE OF SUBMISSION 8/10/00
6. The applicant requests the variance to be in effect for a period of <u>2</u> years from the date of issue. (In general the Agency will approve a variance for only two years. If a longer period is requested a justification must be attached as part of the application.)		
<b>7. PRODUCT DESCRIPTION AND USE</b>		
a. LIST NAME AND MODEL NUMBER(S) Lowell Products Development (LTD) 40mw Q Beam 100MW Q-beam, Nova 3.0, Nova 50		
b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED <input type="checkbox"/> A LASER DISPLAY DEVICE <input type="checkbox"/> A PROJECTOR FOR A LASER LIGHT SHOW <input checked="" type="checkbox"/> A LASER LIGHT SHOW <input type="checkbox"/> OTHER (Specify)	c. <input type="checkbox"/> PROJECTORS ARE INTENDED FOR SALE, LEASE OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS d. PRODUCT IS INTENDED FOR USE IN A <input type="checkbox"/> PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE <input type="checkbox"/> THEATER <input type="checkbox"/> DISCOTHEQUE OR NIGHT CLUB <input type="checkbox"/> PAVILION <input type="checkbox"/> INDOOR ARENA <input type="checkbox"/> OUTDOOR ARENA <input type="checkbox"/> MUSEUM <input type="checkbox"/> OUTDOOR ENCLOSED AREA <input checked="" type="checkbox"/> OTHER (Specify) Bowling Center	
e. PRODUCT IS INTENDED TO BE USED <input checked="" type="checkbox"/> AT ONLY ONE (fixed) LOCATION <input type="checkbox"/> AT A VARIETY OF (moving) LOCATIONS <input type="checkbox"/> OTHER (Specify)	f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION <input type="checkbox"/> MORE THAN 15 DAYS <input type="checkbox"/> MORE THAN 5 BUT NOT MORE THAN 15 DAYS <input type="checkbox"/> LESS THAN 5 DAYS  g. TOUR IS INTENDED TO RUN FOR <input type="checkbox"/> MORE THAN 6 MONTHS <input type="checkbox"/> 1-6 MONTHS <input type="checkbox"/> LESS THAN 1 MONTH <input type="checkbox"/> OTHER (Specify)  h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS <input checked="" type="checkbox"/> FRONT SCREEN PROJECTIONS <input checked="" type="checkbox"/> REAR SCREEN PROJECTIONS <input type="checkbox"/> HOLOGRAPHIC DISPLAYS <input checked="" type="checkbox"/> MULTIPLE REFLECTIONS (multiple channels or diffraction effects) <input type="checkbox"/> AUDIENCE SCANNING <input checked="" type="checkbox"/> REFLECTIONS FROM STATIONARY MIRROR(S) OR MIRRORED SURFACES <input checked="" type="checkbox"/> STATIONARY IRRADIATION OF ROTATING MIRROR BALL(S) OR OTHER MIRRORED SHAPES <input checked="" type="checkbox"/> SCANNING IRRADIATION OF ROTATING MIRROR BALL(S) <input checked="" type="checkbox"/> FIBER OPTIC PROJECTIONS <input checked="" type="checkbox"/> FOG, SMOKE OR OTHER SCATTERING EFFECTS <input type="checkbox"/> OTHER (Specify)	
8. LASER RADIATION LEVELS		
LASER MEDIUM (Ar, He-Ne, etc.)	WAVELENGTHS (nm)	PEAK POWER (Watts)
Argon	455-514 nm	2 Watts
Argon / Krypton	455-670 nm	500 mW
Nd:YAG	532 nm	5 Watts
9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE Scanned: D.C. to 500 Hz      Amplitude: 60 deg., peak to peak		
10. REASON FOR REQUESTING VARIANCE <input checked="" type="checkbox"/> COMPLIANCE WITH THE LIMITS OF 21 CFR 1040.11(c) WOULD RESTRICT THE INTENDED USE OF THE PRODUCT BECAUSE COMPLIANCE WOULD LIMIT THE OUTPUT POWER TO THE EXTENT THAT THE DESIRED EFFECTS WOULD NOT BE SUFFICIENTLY VISIBLE <input type="checkbox"/> OTHER OR ADDITIONAL EXPLANATION (Specify)		

FORM FDA 3147 (3/87)

00V-1465

Var 1



I. X ADVANCE WRITTEN NOTIFICATION WILL BE MADE AS EARLY AS POSSIBLE TO APPROPRIATE FEDERAL, STATE AND LOCAL AUTHORITIES PROVIDING SHOW ITINERARY WITH DATES AND LOCATIONS CLEARLY AND COMPLETELY IDENTIFIED, AND A BASIC DESCRIPTION OF PROPOSED EFFECTS INCLUDING A STATEMENT OF THE MAXIMUM POWER OUTPUT INTENDED. SUCH NOTIFICATIONS WILL BE MADE, BUT NOT NECESSARILY LIMITED TO:

- (1) THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF COMPLIANCE (HFZ 312), 2008 GAITHER ROAD, ROCKVILLE, MD 20850, PROVIDING THE INITIAL AND CLOSING DATES FOR THE FIXED INSTALLATION AND THE ITINERARY FOR MOBILE SHOWS. IN ADDITION, UNLESS ALL ASPECTS OF EACH SHOW HAVE BEEN REPORTED AND THE ACCESSION NUMBERS CLEARLY REFERENCED, EACH NOTICE WILL INCLUDE DETAILED DESCRIPTIONS OF EACH SHOW AND A LISTING OF ALL EFFECTS TO BE PERFORMED IN SUFFICIENT DETAIL TO CONFIRM COMPLIANCE WITH THE REGULATIONS AND THIS VARIANCE.
- (2) THE FEDERAL AVIATION ADMINISTRATION (FAA) FOR ANY PROJECTIONS INTO OPEN AIRSPACE AT ANY TIME (I.E., INCLUDING SET-UP, ALIGNMENT, REHEARSALS, PERFORMANCE, ETC.) IF THE FAA OBJECTS TO ANY LASER EFFECTS, THE OBJECTIONS WILL BE RESOLVED AND ANY CONDITIONS REQUESTED BY FAA WILL BE ADHERED TO. IF THESE CONDITIONS CAN NOT BE MET THE OBJECTIONABLE EFFECTS WILL BE DELETED FROM THE SHOW.
- (3) STATE AND LOCAL RADIATION CONTROL OFFICES/AGENCIES FOR ALL SHOWS TO BE PERFORMED WITHIN THEIR JURISDICTIONS. ALL REQUIREMENTS OF STATE AND LOCAL LAW WILL BE SATISFIED AND ANY OBJECTIONS RAISED BY LOCAL AUTHORITIES WILL BE RESOLVED OR THE EFFECTS DELETED. (LISTS OF FEDERAL AND STATE OFFICES ARE AVAILABLE FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH UPON REQUEST.)

14. REMARKS

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete and correct in the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading or inconsistent in any material way. I have submitted/will submit all reports required by 21 CFR 1002.12 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Bureau of Radiological Health to supply such other information, if it may be necessary to evaluate and act on this application.

15. SIGNATURE

16. NAME (Type or Print)

17. TITLE

Rick Harrington

Manager

## REPORT ON LASER LIGHT SHOW OR DISPLAY\*

## PART 1

## IDENTIFICATION OF MANUFACTURERS

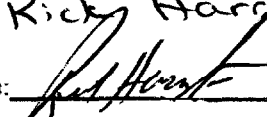
## 1.1 Manufacturer

- a. Name of light show manufacturer: Lowell Products Development, Inc
- b. Address: P.O. Box 446  
Marysville, WA 98270-0446
- c. Area Code and telephone: 425 743-2993

## 1.2 Importer (If applicable)

- a. Name of Importer:
- b. Address: Street  
City  
State Zip Code
- c. Area code and telephone

## 1.3 Name, signature, and title of person preparing this report

- a. Name: Ricky Harrington
- b. Signature: 
- c. Title: Manager

\* Information on laser projectors is to be submitted using "Guide for Preparing Initial Reports and Model Change Reports on Lasers and Products Containing Lasers," HHS Publication FDA 86-8259.

**PART 2****IDENTIFICATION OF REPORT**

2.1 Is this report pursuant to paragraph (c) of 21 CFR 1002.61?

(X) Yes ( ) No

2.2 This report is

(X) an initial report

( ) a model change report

( ) a supplemental report

2.3 If this is a supplemental report, give CDRH accession number and date of the initial or model change report that it supplements.

Accession number: \_\_\_\_\_

Date: \_\_\_\_\_

2.4 Date of this report: 8/8/00

**PART 3  
SHOW NAME**

3.1 What is (are) the name(s) of the light show or display?

Cosmic Bowling

**PART 4  
VARIANCE**

4.1 Attach a copy of your variance application (FDA Form 3147) or, if approved, your variance approval letter (or variance number).

**PART 5  
PROJECTION EQUIPMENT**

5.1 List each projector used in the light show by manufacturer, model number or other designation, and CDRH accession number for the projector if known.

<u>Manufacturer</u>	<u>Model or designation</u>	<u>CDRH accession number</u>
MOBOLAZER	MOBOLAZER ML10	92V-0286

**PART 6****SHOW VENUE**

6.1 The laser light show or display takes place in:

( ) Planetarium or other dome projection structure

( ) Theater

( ) Hotel/Motel ballroom or meeting room

( ) Store displays

( ) Trade show or convention

( ) Discotheque or nightclub

( ) Pavilion

( ) Indoor arena

( ) Outdoor arena

( ) Museum

( ) Outdoor unenclosed area

(X) Other (specify) Bowling Center (over laner)

6.2 The laser light show or display takes place:

(X) at only one (fixed) location

( ) at a variety of (tour) location

( ) other (specify)

**PART 7****SHOW LOCATIONS, DATES, TIMES**

- 7.1 Give specific location(s), date(s), and time(s) for the show, if known.\*

Every Friday and Saturday nights at 9pm

**PART 8****LIGHT SHOW EFFECTS PRODUCED**

- 8.1 The laser light show uses the following laser effects:

- ☒ front screen projections
- ☒ rear screen projections
- ☐ holographic displays
- ☒ multiple reflection/diffraction effects
- ☐ audience scanning, including scanning any accessible, uncontrolled areas
- ☒ reflections from stationary mirrors or mirrored surfaces
- ☒ stationary irradiation of rotating mirror balls or other mirrored shapes
- ☒ scanning irradiation of rotating mirror balls, etc.
- ☒ fiber optic projections
- ☒ fog, smoke, or other scattering effects
- ☐ other (specify)

\* see footnote 1 at the end of this Guide



**PART 9****DIAGRAMS AND DRAWING OF SHOW VENUE**

- 9.1 Provide both plan and elevation drawings with dimensions of the show or display. If the setup varies from show to show, then provide this information for a typical show. Include in the drawings the location of the projector(s) and control panel(s), audience, performer(s), operator(s), mirror(s), mirror balls, display screens (or other targets), and beam termination points.

Show the direct and reflected laser radiation beam paths. Provide the laser radiation levels in each beam including the wavelengths, peak and average power, and scan parameters (if scanned) for the worst case from a human access point of view. Be sure the drawings indicate the minimum separations of the laser radiation fields (or beams) from reference locations in audience and performer areas in both vertical and horizontal directions, and any direct or reflected beams into audience or performer locations.

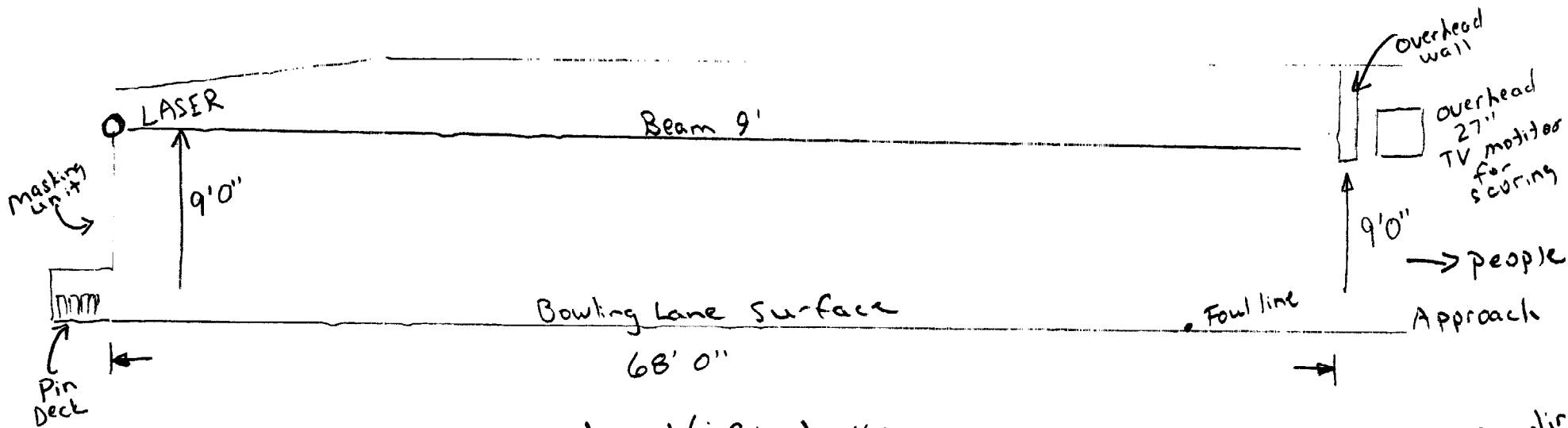
Drawings attached? (X) Yes ( ) No (If "No," explain why)

**PART 10****LASER RADIATION LEVELS**

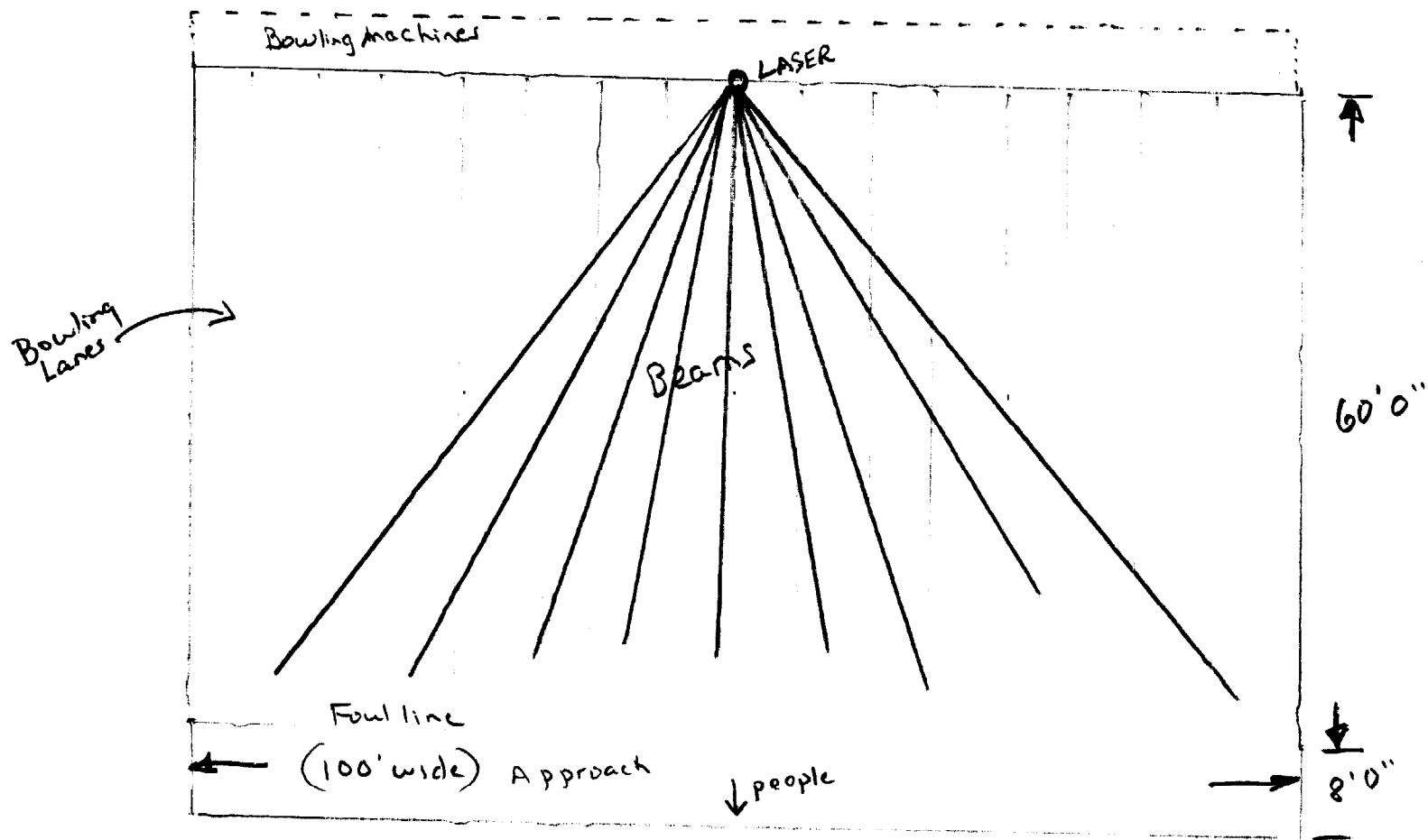
- 10.1 Describe how each of the laser radiation levels, indicated above, were determined. If any levels were derived from calculations rather than directly measured, provide the actual calculation that were made.

Description and calculations enclosed? ( ) Yes (X) No

Assuming the mirrors are 100% reflective, then theoretically the effects produced would be at the same level as the laser being used which could range from 30mW to 1 Watt.



Side View 1/8" scale



Overhead View  
1/16 scale

Family Bowling  
Center  
Fort Dodge, Iowa

**PART 11****SCANNING SAFEGUARDS**

11.1 Will there be audience scanning\* from any of the planned effects?

☐ Yes ☒ No

11.2 Do any of the planned effects require laser radiation to be viewed by operators, performers, or employees?

☐ Yes ☒ No

If the answer to either of the above questions is yes, describe how the radiation levels that reach into audience areas are maintained within the limits of Class I. If Class I limits are maintained by scanning, your description must include details of the required scan failure safeguard, including a discussion of the means of detection of the scanning, the theory of the operation of the scanning safeguard, and its speed of response.

Description attached? ☐ Yes ☐ No (If "No," explain why)

11.3 Will any laser radiation greater than Class I STRIKE BUT NOT BE VIEWED by operators, performers, or other employees?

☐ Yes ☒ No

If "Yes," describe, in detail, the operation of the scan failure safeguard or other means which will prevent exposure to beams exceeding Class II. If a scan safeguard is used, include a discussion of the detection of scanning, the theory of operation, and the speed of response of the safeguard. If other means are used, such as pressure pads or infrared beams, describe in detail as well.

Description attached? ☐ Yes ☐ No (If "No," explain why)

\* see footnote 2 at the end of this Guide

## PART 12 OPERATOR CONTROLS

12.1 Is the show under the continuous control of an operator?

☒ Yes                      ☐ No

12.2 Does the laser operator perform tasks in addition to operation of the laser projector?

☒ Yes                      ☐ No

(If "Yes," describe those tasks) operator also is the DJ, operates other lights and music

12.3 Can the operator see all the propagating beam paths, their terminations, and the audience at all times during the performance?

☒ Yes                      ☐ No (If "No," explain how adequate surveillance is provided):

12.4 Do any other personnel assist in providing surveillance of the laser display?

☒ Yes                      ☐ No

If "Yes," state the number of persons, their identification, and how they assist in providing surveillance. 2 others monitor laser operations (1) counter person  
(2) Floor person

Information attached? ☒ Yes                      ☐ No (If "No," explain why)

Both employees watch for laser malfunctions and safety guidelines as announced before each show

12.5 What qualifications are required of laser operators for your show?

They must attend an introductory training class where they learn about the system, how to set up a show and most important, they learn about safety. They are also given copies of the CDRH regulations concerning lasers. We also provide monthly refresher courses. They are required to serve a minimum of six hour internship as an assistant to a qualified operator.

Will train to these guidelines

\* see footnote 3 at the end of this Guide

**OPERATOR CONTROLS (Continued)**

- 12.6 If your show is not under the continuous control of an operator, is a person designated to be responsible for the immediate termination of the laser radiation in the event of equipment malfunction, audience unruliness, or other unsafe conditions?

( ) Yes ( ) No (X) Not applicable

(If "No," explain alternate control)

- 12.7 How is this person designated? What are his or her other duties?

- 12.8 What qualifications are required of this person?

**PART 13****PROJECTION EQUIPMENT CONTROLS**

- 13.1 Are one or more readily accessible controls provided to immediately terminate laser radiation?

(X) Yes ( ) No

Number of controls: 2 One remote interlock

- 13.2 Describe the location of these controls and their operation relative to your show.

The laser projector is equipped with a remote interlock, which has a key switch to terminate laser emission upon removal of the key or if the remote interlock is disconnected from the projector. The remote interlock is located next to the laser projector control board and can be accessed immediately.

- (1) rocker electrical switch to turn power on and off  
(2) remote interlock switch

Both located in close proximity  
(3) key switch at unit itself accessible by mechanic on duty from the machine area of bowling center

**PART 14****TEST PROCEDURES**

- 14.1 Attach a copy of the written setup, alignment, and test procedures to be followed prior to the operation of the laser light show at each location (see sample checklist for laser light shows in Appendix).

Procedures attached? ☒ Yes ☐ No (If "No," explain why.)

- 14.2 When are these setup, alignment, and test procedures performed? *Morning of each show*  
Prior to the establishment opening for business, when no patrons are present. *(yes)*

- 14.3 What laser radiation levels are used during setup, alignment, and checkout?

30 - 40 milliwatts

- 14.4 Is a record of the results of the setup, alignment, and test procedures maintained?

☒ Yes ☐ No

If "No," explain how adequate quality assurance is maintained.

**NOTE:** Adequate recordkeeping would include, but not be limited to: (1) sketches showing the location of the laser projector(s), operator(s), performer(s), audience, beam paths, viewing screens, wall mirrors, mirror balls, and other surfaces that may be struck by the laser beams; (2) information on scanning patterns, velocity, and frequency; and (3) laser radiation levels used in each effect.

**PART 15****NOTIFICATION PROCEDURES**

- 15.1 What procedures are followed for notification of appropriate Federal (CDRH, FAA), State, and local agencies?

A show notification letter will be sent to the CDRH and State Radiological Health Branch 30 days prior to commencement of the show.

Procedures and/or form letters attached? (X) Yes ( ) No (If "No," explain why)

- 15.2 What Federal, State, or local agencies are notified or would be notified?

List of agencies attached: (X) Yes ( ) No (If "No," explain why)

Center for Devices and Radiological Health  
Office of Compliance  
Attn: EPRC, HF2-312  
2098 Gaither Road  
Rockville, Maryland 20850  
Phone: (301) 594-4654 FAX: (301) 594-4672

## FOOTNOTES

### 1. Show notification:

Provide the location(s), date(s), and time(s) for this show if this information is known at the time this report is submitted. If not, advanced written notification must be made as early as possible to appropriate Federal, State, and local authorities. To be considered timely, this written notice must be submitted 30 days prior to the opening of the show. When the show dates become known to the manufacturer less than 30 days prior to the show date, the required information must be provided verbally by phone to CDRH. A confirming formal written notice, including the date of the phone notification and the name of the CDRH individual to whom the information was given must be submitted to CDRH within 14 days.

CDRH must be notified of every show that your firm intends to produce. If notifications are not routinely received in a timely manner your variance may be revoked.

### 2. Audience scanning:

Audience scanning is considered any direct or reflected beams or levels of radiation exceeding Class I reaching areas in which the audience is permitted. Scattered radiation coming from diffuse reflectors such as fog, smoke, mist or similar diffusing media is not considered audience scanning. However, this scattered radiation must also be below Class I levels if it reaches into audience areas. A scanning safeguard is required whenever a laser light show includes audience scanning.

### 3. Qualifications:

Holders of variances are required by the variance to employ trained operators or to assure that the operators receive adequate training to qualify them for the safe use of the laser projection system and presentation of the light show effects. Useful information, training films, reference books, and programs on the safe use of lasers may be obtained from the Laser Institute of America (LIA) 5151 Monroe Street, Toledo, Ohio 43623; and from the American National Standards Institute, 1430 Broadway, New York, New York 10018 (request ANSI Standard Z136.1).



## **LASER SHOW CHECKLIST AND DOCUMENTATION**

All items must be brought to a satisfactory state before being checked off

### **A. IDENTIFICATION**

1. Name of show :
2. Location of show :
3. Date(s) and time(s) of show :
4. Operator responsible for safety of show :
5. Manufacturer of the laser show projector / display device:  
MOBOLAZER, Inc.  
790 Hampshire Road, Unit D  
Thousand Oaks, California 91341  
(805) 230-2166

### **B. EQUIPMENT CHECKS**

1. Are all protective housings in place with tight fit?
2. Is the projector secured rigidly in place?
3. Before activating the laser, check that all beam shutters are operable and are left in the closed positions.
4. Make sure that the laser cannot be energized without the key and that the key removal terminates operation.
5. Check that all accessory optics such as mirrors and targets are secured firmly in place.
6. Energize the laser at the lowest possible power (without allowing the laser light to emerge and with shutters closed).
7. Confirm that all emission indicators and the emission delay operated properly.
8. Verify that all required labels are in place and visible on the projector:
  - ( ) Certification (Front lower right side of projector)
  - ( ) Identification (Front lower left side of projector)
  - ( ) Aperture (Top rail of projector)
  - ( ) Non-interlocked (Front and side panels of projector)
  - ( ) Warning logotype (Front upper right side of projector)

## C. ALIGNMENT CHECKS

1. Evacuate all but essential personnel from facility. These checks must be performed with no audience present.
2. Make sure you have visual control of the entire projection space from your operating location (especially the audience space) and that areas are adequately secured (see the current ANSI Z136.1 standard for guidance).
3. Operate the laser at the lowest possible power, open shutters, and perform alignments.
4. Perform physical survey to confirm that beams exceeding Class I will be separated from the audience by the minimum distances required. (In general, for shows under operator control, a 3 meter vertical separation and a 2.5 meter horizontal separation from audience locations are required. For shows not under continuous operator control, a 6 meter vertical and 2.5 meter horizontal separation would be required.)
5. Review your proposed projections with venue management to be certain that the audience will not be permitted access to locations resulting in a violation of item 4 above.
6. Operate the projector at the power required by the show, making sure that there are no spurious projections into unintended areas and that the conditions of item 4 above are maintained. Determine and record the power levels in accordance with the levels reported in Part 2 of your laser light show report.
7. Confirm that all projectors and optics are rigidly secured and cannot be disturbed during subsequent operations or during the show itself.
8. Check for operation and proper setting of all devices related to safety, including:
  - ( ) beam blocks
  - ( ) scanning safeguards
  - ( ) emergency stop controls
9. Maintain continuous surveillance of the projectors and all optics between the times of alignment and the show to be certain that the alignment of the projector and optics is not disturbed.

## Laser Show Checklist and Documentation Page 3

**D. MEASUREMENT / PARAMETRIC CHECKS**

1. List the effects to be performed.
  - (a) Beams
  - (b) Linear Diffraction gratings
  - (c) Front Projections
  - (d)
  - (e)
2. For each effect, give, if applicable, time duration, intended and measured power in beams, scan frequency and amplitude, and identification of measuring instrument used.
  - (a) Beams < 2W
  - (b) Linear Diffraction gratings < 2W
  - (c) Front Projections < 2W, 0 to 300 Hz, 10 deg. vertical, 60 deg. horizontal
  - (d)
  - (e)

**E. ADMINISTRATIVE CHECKS**

1. List the name and title of the individual responsible for safety at the show facility:
2. List those agencies you have notified of your show.
  - (a) Attach a copy of your notifications.
3. Attach plan and elevation drawings showing the locations of all projectors, external optics, projections, and audience.

**NOTE:** Safety considerations mandate that you account for all specular reflections and that the operator have visual control of all projections at all times.

## **LASER SAFETY TRAINING**

### **Checklist**

- ☐ Never scan audience with laser beams
- ☐ Permit only authorized personnel to operate the lasers
- ☐ Always keep laser beam path 3 meters above the ground
- ☐ Do not permit tracking of vehicles or aircraft
- ☐ Assure that individuals **do not** look into the laser beam
- ☐ Do not aim laser beam at any mirror-like surfaces other than Mobolazer bounce mirrors.
- ☐ Always keep laser located in well controlled area
- ☐ Never attempt to service the laser yourself
- ☐ Laser Operation Checklist has been delivered and operator(s) instructed on use
- ☐ Laser Safety Guide delivered to operator(s)

The above laser safety information was provided to \_\_\_\_\_

on \_\_\_\_\_ 1997.

Acknowledged:

NAME OF RECEIPTENT \_\_\_\_\_

\_\_\_\_\_

# MOBOLAZER PROJECTOR PRE-PERFORMANCE CHECKLIST

CDRH requires that all items be checked for compliance prior to every performance.

These records are to be maintained for the duration of the installation.

PERFORMANCE	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Beam Aperture 1															
" " 2															
" " 3															
" " 4															
" " 5															
" " 6															
" " 7															
" " 8															
" " 9															
" " 10															
Shutter Functional															
Key Interlock Functional															
Emission Indicator Functional															
Labels Present															
OPERATOR'S INITIALS															
DATE															

INS CENTER  
687  
VE. SOUTH  
E, IA 50501



0000



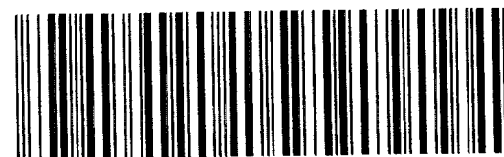
20857

U.S. POSTAGE  
PAID  
FORT DODGE, IA  
50501  
AUG 10, 00  
AMOUNT

**\$3.55**  
00077028-03



United States Postal Service  
**DELIVERY CONFIRMATION**



0304 7990 0002 9183 9378

FDA

Attn: Hearing Clerk  
Dockets Mgmt Branch (HFA-308)  
12420 Parklawn Drive, Room 1-23  
Rockville, MD 20857